

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

REC'D 23 MAY 2005

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To:

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/IB2005/050407

International filing date (day/month/year)
31.01.2005

Priority date (day/month/year)
10.02.2004

International Patent Classification (IPC) or both national classification and IPC
A61N1/39

Applicant
KONINKLIJKE PHILIPS ELECTRONICS N.V.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/B2005/050407

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
☐ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material:
☐ in written format
☐ in computer readable form
 - c. time of filing/furnishing:
☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
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Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-15, 17, 18
	No: Claims	16
Inventive step (IS)	Yes: Claims	
	No: Claims	1-18
Industrial applicability (IA)	Yes: Claims	1-18
	No: Claims	

2. Citations and explanations

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item V.

1 Reference is made to the following documents:

- D1: US-A-5 662 690 (COLE ET AL) 2 September 1997 (1997-09-02)
- D2: US 2003/055478 A1 (LYSTER THOMAS D ET AL) 20 March 2003 (2003-03-20)
- D3: US 2003/216785 A1 (EDWARDS D. CRAIG ET AL) 20 November 2003 (2003-11-20)
- D4: US-A-5 792 190 (OLSON ET AL) 11 August 1998 (1998-08-11)
- D5: US 2003/028219 A1 (POWERS DANIEL J ET AL) 6 February 2003 (2003-02-06)
- D6: US-A-5 993 219 (BISHAY ET AL) 30 November 1999 (1999-11-30)
- D7: US 2002/143366 A1 (HERLEIKSON EARL CLARK) 3 October 2002 (2002-10-03)

2 INDEPENDENT CLAIM 1

2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of **claim 1** does not involve an inventive step in the sense of **Article 33(3) PCT**.

The document D1 is regarded as being the closest prior art to the subject-matter of claim 1, and discloses (the references in parentheses applying to this document) (see fig. 2):

An external defibrillator (130) selectably usable in one of a therapy mode and a training mode (*see column 1, line 58*), when in the training mode, having a plurality of training state notifications (*see column 4, line 65 - column 5, line 55*), and adapted for electrical coupling with an electrode (140) arrangeable on a release liner, the electrode electrically conductive and configured for placement of a subject, comprising:

- an energy source (132);
- an electrode interface (138) responsive to the electrode;
- an energy delivery system (136) operable to selectively deliver electrical energy from the energy source to the electrode via the electrode interface;
- a state identifier, identifying, when the electrode is electrically coupled to the electrode interface (*a state identifier is implicitly disclosed since different operational states are identified: checking of electrode attachment; of electrode operability; analysing; providing shock*) (*see column 4, line 65 - column 5, line 55*);
- a controller (134), operative in the training mode, prior to placement of the electrode on

the subject, to advance the external defibrillator from a first training state to a second training state (see column 5, lines 9-35: 1st training state= checking attachment and operability of electrodes; 2nd training state= placing & analysing);

- a user interface (181, 182, 183, 184), operative in the training mode to issue a training state notification indicating that the external defibrillator has advanced from the first training state to the second training state (see column 5, lines 9-35).

The subject-matter of claim 1 therefore differs from this known external defibrillator in that the state identifier identifies *a degree of electrical connectivity* along an electrical path including the electrode, and that the advancement from the first training state to the second training state occurs when the state identifier identifies a predetermined *degree of electrical conductivity* along the electrical path.

The problem to be solved by the present invention may therefore be regarded as how to verify whether defibrillation electrodes are ready for use.

2.2 In view of D2 the solution proposed in claim 1 of the present application cannot be considered as involving an inventive step (Article 33(3) PCT) for the following reasons: D1 already discloses that, before the electrodes are placed on the subject, the connectivity and operability needs to be checked (see column 5, lines 9-22), without specifying how this test should be done.

D2 however discloses a test for checking the condition of electrodes of an external defibrillator (see par. 2), based on the impedance measured between two electrodes (see par. 27). The electrodes are considered to be inadequate when this impedance exceeds a predetermined value, and to be adequate otherwise (see par. 245).

Switching to another state depending on the electrical conductivity is thus known from D2. The skilled person would therefore regard it as a normal option to include this feature in the electrode test described in document D1 in order to solve the problem posed, thereby arriving at an external defibrillator according to claim 1.

3 INDEPENDENT CLAIM 15

Since the subject-matter of **independent claim 15** corresponds to the subject-matter of claim

1, the same reasoning as given for claim 1 will apply *mutatis mutandis*. Therefore claim 15 is also not considered to meet the requirements of the PCT with respect to inventive step.

4 INDEPENDENT CLAIM 16

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of **claim 16** is not new in the sense of Article 33(2) PCT. Document D2 discloses (the references in parentheses applying to this document):

A method for performing defibrillator training (*although the disclosed device is not explicitly specified to be a training device, it still can be used for training, e.g. on a mannequin*) comprising the steps of:

- providing an automatic external defibrillator training device;
- providing a pair of training electrodes in electrical communication with said training device;
- sensing an impedance between said pair of training electrodes (see par. 27);
- advancing a training rescue based on said sensed impedance (see pars. 242-246).

5 DEPENDENT CLAIMS 2-14, 17, 18

Dependent **claims 2-14, 17, 18** do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step (**Article 33(3) PCT**):

- claims 2, 17: see D2, par. 27;
- claims 3, 4: the problem of not removing the release liner from the electrodes is well known to the skilled person (see e.g. D3, par. 31, or fig. 12, step 250). D2 discloses a method to determine whether this liner is still on the electrodes (see par. 169, see claim 164). Therefore the skilled man would also implement this test when verifying the electrode attachment & operability in the device of D1.
- claim 5: see D1, column 5, lines 21, 22;
- claim 6: normal design option (see e.g. D3, par. 46, or D4, column 6, lines 20-25);
- claim 7: see D5, par. 30 and par. 73: the training cartridge sends other electrical signals which ensures that the processor will work in testing mode;
- claims 8, 9: see D2, pars. 158-169;
- claims 10, 11: normal design option (see e.g. D7, pars. 53-59);
- claim 12: see D1, column 13, lines 34-42;
- claim 13: see D1, column 1, lines 26-32;

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AUTHORITY (SEPARATE SHEET)**

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- claims 14, 18: see D6, column 3, lines 42-66.

Re Item VIII.

Claim 4 does not seem to meet the requirements of **Article 6 PCT** in that the matter for which protection is sought is not clearly defined. The claim attempts to define the subject-matter in terms of the result to be achieved (verification whether electrode is removed from its package), which merely amounts to a statement of the underlying problem, without providing the technical features necessary for achieving this result.

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- claims 8, 9: see D2, pars. 158-169;
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- claim 12: see D1, column 13, lines 34-42;
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- claims 14, 18: see D6, column 3, lines 42-66.

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